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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,386	06/23/2005	Yoshimochi Kurokawa	3749-0105PUS1	3319
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BIRCH STEWART KOLASCH & BIRCH			ROBERTS, DARIN	
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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/540,386	<b>Applicant(s)</b> KUROKAWA, YOSHIMUCHI	
	<b>Examiner</b> Darin R. Roberts	<b>Art Unit</b> 3762	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/23/05</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Objections***

Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

### ***Claim Rejections - 35 USC § 112***

**Claim 3 is rejected** under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In reference to ***claim 3***, the term "long pulse stimulation" in claim 3 is a relative term, which renders the claim indefinite. The term "long pulse stimulation" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The phrase "long pulse stimulation" found in line 1 of claim 3 is a vague and does not specify what length of stimulation is seen as long.

### ***Claim Rejections - 35 USC § 101***

Claims 1 & 2 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1 & 2 are directed toward the claiming

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of structures being in contact with or implanted within the body. Such claiming amounts to an inferential recitation of the body, thus rendering the claim non-statutory.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 1 & 2 are rejected** under 35 U.S.C. 102(e) as being anticipated by Boveja et al. (US 6879859 B1).

In reference to **claims 1 & 2**, the Boveja et al. publication teaches the use of a gastric electrical stimulation apparatus having an electrical stimulation device that can be described as a pulse generator located outside of the body (see abstract), as well as an external coil connecting to the internal stimulation device (see fig. 6). The Boveja et al. publication also teaches the use of an internal coil which is implanted in the body and receives electricity from the external coil by transcutaneous energy transmission (see fig. 6) as well as a waveform rectifier circuit connecting to the internal coil (see fig. 6), and electrodes capable of making contact with the gastric wall, and are connecting to the waveform rectifier circuit (see column 12, lead line 50-59 & fig. 1E). The Boveja et al. device is also inherently capable of being use on gastroparesis patients and can

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stimulate for extended periods of time (see column 15, lead lines 16-19). Boveja et al. also teaches stimulation of the stomach via stimulation of an undamaged portion of the vagus nerve (see fig. 1E)

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1-4 are rejected** under 35 U.S.C. 103(a) as being unpatentable over Loeb et al. (US 20020123774 A1) in view of Boveja et al. (US 6879859 B1).

In reference to **claims 1-4**, the Loeb et al. publication teaches the use of a gastric electrical stimulation apparatus having what can be describes as an external pulse generator located outside of the body (see pp. [0012]), and an external coil connecting to the pulse generator (see fig. 1), because the Loeb et al. device possesses an external coil used for communication with the implanted device, the Loeb et al device must inherently possess an internal coil or something of the like that is implanted in the body and is capable of receiving electrical signals from the external coil by transcutaneous energy transmission. The internal information receiving apparatus (or coil) and electrodes of the Loeb et al. device are positioned in contact with the gastric wall (see fig. 1 & claim 10). However the Loeb et al publication does not teach the use of a waveform rectifier. The Loeb et al. device is inherently capable of use on

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gastroparesis patients, and is inherently capable of stimulating for a period of time that can be seen as long or extended.

The Boveja et al patent teaches the use of a wave for rectifier during gastric stimulation and the use of certain stimulation parameters (see column 15, lead lines 16-38).

Thus it would have been obvious to one of ordinary skill in the art to adjust the stimulation parameters and use the Boveja et al. waveform rectifier in conjunction with the Loeb et al. device to produce the appropriate waveform and allow for optimal treatment.

### ***Conclusion***

The **prior art made of record and not relied upon** is considered pertinent to applicant's disclosure. The examiner wishes to cite the **Swoyer et al. (US 6876885 B2)** patent because of its reference to internal gastric stimulation and its use of an external stimulation device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darin R. Roberts whose telephone number is (571)272-5558. The examiner can normally be reached on 7:30am to 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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6/12/06